

September 20, 2005

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Levinson:

The Wall Street Journal, in an August 16, 2005 article, examined allegations that universities misuse federal grant money received from the National Institutes of Health (NIH). Some of these allegations have resulted in recent multi-million dollar settlements between NIH university grantees and the U.S. Department of Justice. For example, in a complaint-in-intervention filed June 15, 2005, the U.S. Attorney's Office for the Southern District of New York ("U.S. Attorney's office") alleged that a university grantee failed to comply with NIH guidelines for clinical research programs and made false statements in applications to NIH for renewal of its General Clinical Research Center grant.

In particular, the U.S. Attorney's office highlighted the disparities between the number of research activities projected by the grantee in its grant applications or grant continuation applications to NIH, and the actual number of research activities performed by the grantee after receiving the NIH grant money, as reflected in the grantee's internal data, and to some extent, the grantee's annual progress reports submitted to NIH. For example, one year the university grantee projected an increase in the number of in-patient days awarded under the grant based on four protocols pending that would require the availability of additional bed days. One of these protocols was never used. Another protocol never had any patient admissions under it. Another protocol never used any in-patient days in the next fiscal year and only one day was ever used under this protocol in the following fiscal year. The fourth protocol had no in-patient visits under the protocol "ever" and according to the U.S. Attorney's office, "it is highly unlikely that any in-patient visits the [next fiscal year] were truly anticipated."

In light of concerns such as those alleged by the U.S. Attorney's office and your office's jurisdiction and past activity in this area, we request that the Office of Inspector General (OIG) examine whether there are widespread disparities between the numbers of research activities grantees projected to obtain taxpayer funds from the NIH and the numbers of research activities actually performed with these funds. To that end, we further request that the OIG conduct an audit of some of the largest NIH clinical research center grants to review the number of research activities each respective institution projected to the NIH and what research activities these institutions actually performed. The OIG may also want to consider designing this audit to capture other kinds of discrepancies, such as false statements, improper accounting, improper charges to NIH grants, and even fraudulent double-billing of the Medicaid program for in-patient fees charges incurred in connection with protocols performed under these clinical research center grants.

The alleged misuse of NIH grant funds raises serious public policy concerns of waste, effectiveness, and integrity of taxpayer-supported research programs. Thank you in advance for your consideration of this request. If you have any questions, please contact Alan Slobodin of the Committee staff at (202) 225-2927.

Sincerely,

Joe Barton
Chairman

Ed Whitfield
Chairman
Subcommittee on Oversight
and Investigations

cc: The Honorable John D. Dingell, Ranking Member
The Honorable Bart Stupak, Ranking Member
Subcommittee on Oversight and Investigations
The Honorable Elias A. Zerhouni, M.D., Director, NIH